AUG 1 3 2002

K021999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

GRIPPER PLUS™ Needle

June 18, 2002

I. GENERAL INFORMATION

Applicant's Name and Address:	Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Lisa J. Stone Manager, Regulatory Affairs
Common/Usual Name:	Administration Set
Proprietary Name:	GRIPPER PLUS™ Needle
Equivalence Device Comparison:	GRIPPER® Needle (manufactured by Deltec, Inc.) Huber Plus Safety Infusion Set (manufactured by NowMedical)

II. DEVICE DESCRIPTION

The GRIPPER PLUS™ Needle is similar in design to the current GRIPPER® Needle, with the incorporation of a passive needle stick protection feature. The protection feature is made of a base and arm with a hinge on one end. As the needle is removed from a portal the hinge allows the needle to be pulled back and locked into the capture well in the base. There is an audible "click" when the needle is captured. The device is designed to help protect against exposure to bloodborne pathogens caused by accidental needlestick injuries. It does not protect against other routes of bloodborne pathogen transmission. The needle tip is fully protected after deployment of the needle stick protection feature and will not disengage with normal handling such that the needle tip becomes exposed.

The needle will be offered in various needle gauges and lengths, and with or without a slit-septum injection site cap.

III. INTENDED USE OF THE DEVICE

The GRIPPER PLUS™ Needle is indicated for the administration into or withdrawal of fluids from implanted ports. It is designed to help protect against exposure to bloodborne pathogens caused by accidental needlestick injuries.

IV. DEVICE COMPARISON

	GRIPPER PLUS™ Needle	Huber Plus Safety Infusion Set	GRIPPER® Needle
MANUFACTURER	Deltec, Inc.	NowMedical	Deltec, Inc.
INDICATIONS FOR USE	The GRIPPER PLUS™ Needle is indicated for the administration into or withdrawal of fluids from implanted ports. It is designed to help protect against exposure to bloodborne pathogens caused by accidental needlestick injuries.	To be used with implanted vascular ports.	Intended for the administration into or withdrawal of fluids from implanted ports.
NONCORING NEEDLE	YES	YES	YES
NEEDLE-STICK PREVENTION FEATURE	YES	YES	NO
NEEDLE GAUGES	22 20 19	22 20 19	22 20 19
NEEDLE LENGTHS (inches)	0.625 0.75 1.0 1.25	0.5 0.75 1.0 1.25 1.5	0.625 0.75 1.0 1.25
NEEDLE MATERIAL	Stainless Steel	Stainless Steel	Stainless Steel
TUBING DIMENSIONS (Nominal) I.D. O.D. Length	 0.047 in. 0.103 in. 8.0 in.	 0.046 in. 0.091 in. 9 in.	 0.047 in. 0.103 in. 8.0 in.
TUBING MATERIAL	PVC plasticized with TOTM	PVC (non-DEHP)	PVC plasticized with TOTM
AVAILABLE WITH OR WITHOUT INJECTION SITE	YES	YES	YES

V. SUMMARY OF STUDIES

A. Functional Testing

In-vitro testing and simulated use testing was conducted in accordance with the FDA "Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Prevention Features," dated March 1995.

Biocompatibility testing was conducted on the device components.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the GRIPPER PLUS™ Needles due to their similarity in materials, design and function to the current GRIPPER® Needle and Huber Plus Safety Infusion Set. The device was evaluated by health care professionals during a simulated use test and was found to be acceptable for its intended use.

C. Conclusion Drawn from the Studies

The results of the testing indicated that the GRIPPER PLUS™ Needles function according to specifications and the materials used in the device are biocompatible. Simulated use testing indicated that the device's protection feature successfully activated during all attempts. Therefore, this product is considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Mr. Edward W. Numainville
Vice President, RA/QA
SIMS Deltec, Incorporated
1265 Grey Fox Road
Saint Paul, Minnesota 55112

Re: K021999
Trade/Device Name: GRIPPER PLUS™ Needle
Regulation Number: 880.5440 and 880.5570
Regulation Name: Intravascular Administration Set and Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FPA and FMI
Dated: June 18, 2002
Received: June 19, 2002

Dear Ms. Numainville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

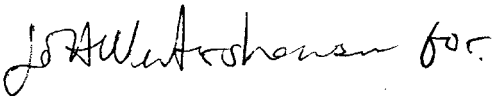
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021999

510(k) Number (if known): _____

Device Name: GRIPPER PLUS™ Needle

Indications for Use:

"The GRIPPER PLUS™ Needle is indicated for the administration into or withdrawal of fluids from implanted ports. It is designed to help protect against exposure to bloodborne pathogens caused by accidental needlestick injuries."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

Rebecca Cucente

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021999